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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,382	03/31/2000	Alison A. McCormick	LSB-001/CIP	9680

7590 01/26/2005

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WASHINGTON, DC 20036

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/539,382	MCCORMICK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher H Yaen	1642	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 54,56,60-64,66,67,69,72,73 and 76-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54,56,60-64,66,67,69,72,73 and 76-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

**Re: McCormick *et al***

**Priority Date: 24 September 1999**

1. The amendment filed 10/28/2004 is acknowledged and entered into the record. Accordingly, claims 1-53,55,57-59,65,68,70-71, and 74-75 are canceled without prejudice or disclaimer.
2. Claims 54,56,60-64,66-67,69,72-73, and 76-86 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Maintained - 35 USC § 103***

4. The rejection of claims 54,56,60-64,66-67,69,72-73, and 76-86 as being obvious over Casper *et al* in view of Fiedler *et al* and Ladner *et al* under 35 USC § 103 is maintained for the reasons of record. Applicant argues that the claimed recitations do not describe preparation methods but instead directly impact the nucleic acid sequence. Specifically, applicant points to the use of sequences encoding expression of the nucleic acid sequence in plants and indicates that such sequences are structural elements found within the claimed composition. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Those of skill in the art would find it obvious to modify the sequences in order to express the nucleic acid sequence in plants because sequences such as promoter sequences for mammalian expression will not function in a plant expression system. As such, one

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of skill would modify the expression sequences deemed competent to express recombinant proteins in specific expression systems. For example, to express a protein in mammalian cells, it would be routine for those of skill in the art to use a mammalian promoter sequence. Likewise, to express recombinant proteins in a plant system one of skill in the art would modify their sequences to incorporate a plant promoter sequence. As such, one of skill in the art would only need sufficient motivation to do so

Casper *et al* teach that when scFv antibodies derived from B cell lymphomas are produced in different expression systems (see page 3700), such as mammalian and bacterial systems, they tend to produce lower yields of scFv antibody. Thus one of skill in the art would find it obvious as evidenced by Casper *et al* to use other means of production so as to increase the of total yield of the scFv. Fielder *et al* teaches the production of scFv antibodies in tobacco plants using a plant expression vector. Fiedler *et al* specifically teach that the expression of nucleic acid vectors encoding scFv antibodies in plants produces higher yields of antibody, provides long term storage means, and produces functionally active antibodies. Thus one of skill in the art would find it obvious to modify the nucleic acid sequence of Casper *et al* to incorporate expression sequences for plants in order to express the scFv in plants as outlined by Fiedler *et al*. The motivation resides in the fact that the expression of the scFv in the plant system would provide higher quantities of scFv. As such, the combination of the references are still deemed obvious over the instantly claimed invention.

Applicant additionally argues that the linkers of the claimed invention are repeated patterns of degenerate triplet nucleotides while that of the recited Tang *et al*

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reference teaches randomized linkers. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejections of record. As indicated in the previous office action, the use of linkers is conventional in the art and serve the purpose of creating flexibility in the expressed protein. Tang *et al* teaches several linker peptides (see page 15684) that fall within the scope of the claimed linkers (see table 1). In addition, one of skill in the art would chose those linkers that are deemed proper for the purpose it is intended to serve. As such, the use of randomized linkers set forth according to the instantly claimed invention is still deemed obvious.

And finally, Applicant argues that none of the references teach that the immunoglobulins produced in the plant are capable of eliciting an immune response. Applicant's arguments have been carefully considered but are not deemed persuasive because the invention is drawn to a product and the intended use of the product (i.e. to elicit an immune response) is viewed as an intended use of which is not a patentable aspect.

Therefore in view of the obviousness of the plant expression sequences, and the use of linkers, the claims of the instantly claimed invention are still deemed obvious over Casper *et al* in view of Fiedler *et al* and Ladner *et al*.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 10/28/2004.**

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**Conclusion**

**No claim is allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

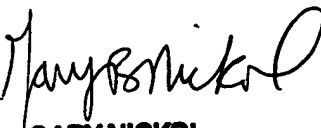
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
January 18, 2005

  
**GARY NICKOL**  
**PRIMARY EXAMINER**